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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,427	03/17/2004	Gustavo C. Rodriguez	31162A	3861

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,427	RODRIGUEZ, GUSTAVO C.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/18/06 & 5/8/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-26 ARE PRESENTED FOR EXAMINATION

Applicant's Amendments filed April 18, 2006 and May 8, 2006 have been received. The latter amendment, being in correct form as to the claims, has been entered into the application. Accordingly, the specification has been amended at page 1 and claims 2-26 have been added.

In view of the amendments and comments provided by Applicant, especially respecting the dosage of the progestin set forth in the previous Office action dated October 12, 2005, (upon review of the previous Office action, the Examiner apparently misread the required dosage of levonorgestrel as at least 0.25 mcg rather than the actually claimed dosage of at least 0.25 *mg*; the Examiner regrets this oversight), the objection to the specification and rejection of claim 1 under 35 U.S.C. § 102(b), as set forth in the previous Office action at pages 2-3, are *withdrawn*.

Specification

The specification at page 1 is objected to as containing a minor informality. The filing date of Application Serial No. 09/528,963 should be inserted following the first instance of this application at page 1, line 1 of the specification, (see Applicant's amendment to the specification filed April 18, 2006).

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlstrom et al., (abstract only, newly cited by the Examiner).

Carlstrom et al. teach an oral contraceptive containing 20 μg ethinylestradiol, (EE), and 250 μg levonorgestrel, (LNg), which was administered daily during the cycle of women having a cycle length of 28 ± 2 days (e.g., see the first paragraph of the abstract) thus meeting the present claim requirements for a daily dosage comprising at least 0.25 mg LNg and an estrogen dosage which does not exceed 25 mcg EE equivalents, or 20 mcg EE equivalents.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen, (U.S. Patent No. 4,855,305, newly cited by the Examiner) in view of Gast, (U.S. Patent No. 5,747,480, already of record).

Cohen teaches an oral contraceptive which comprises melatonin, (i.e., not excluded from the present claims which recite "comprises"), a progestogen, such as levo-norgestrel, (LNg; col. 4, lines 59-60) and an estrogen, such as ethinylestradiol, (EE; col. 5, line 52). The contraceptive is to be administered as part of a regimen which based on a 28 day cycle, (col. 4, lines 61-66). The patentees teach a regimen in which the progestogen is administered for about 21 days, (col. 5, lines 12-13), along with daily administration of the estrogen, which is also administered for 21

of the 28 days, (col. 5, lines 61-64). The regimen is further taught to include a period of time in which a placebo is administered, (e.g., see col. 5, lines 6-10 and col. 6, lines 44-48).

Regarding the amounts of the progestogens and estrogens, the patentees teach that the progestogen dosage depends on the particular compound to be administered, i.e., to account for the differing potencies of the different progestogen compounds, and may range from "about 7.5 μg to about 2500 μg per day", (col. 5, lines 22-24 and 27-37). The estrogen dosage is taught to range from "about 2 μg to about 100 μg per day", (col. 5, lines 64-68) and is taught to vary depending on the potency of the given estrogen compound. It is highlighted that ethinylestradiol is twice as potent as mestranol, (col. 6, lines 2-3).

The differences between the above and the claimed subject matter lies in that the patentees fail to highlight the presently claimed daily and cumulative LNg and EE dosages, (e.g., one daily dosage having at least 0.5 mg LNg and no more than 15 mcg EE equivalent, [claim 10] or a regimen which comprises 20-35 daily dosages and where the total LNg dosage exceeds 10 mg, [claim 17].

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because of the following reasons. A person of such skill would have been motivated to appreciate the following dosage calculations in order to practice the invention as disclosed by Cohen with differing progestogen and estrogen compounds.

Claim 24 of Cohen limits the estrogen compound of his claim 18 or 21 to include the two compounds for which relative potencies have been disclosed, i.e., ethinylestradiol and mestranol.

Claim 18 of Cohen is limited to a dosage amount of estrogen of from about 2 mcg to about 1000 mcg per 70 kg of body weight per day by his claim 19. Thus, a dosage of either 2-1000 mcg of either ethinylestradiol or mestranol is disclosed by the patentee. If one considers the dosage to be of ethinylestradiol, such would equate to from 2 to 1000 mcg EE, which meet the presently claimed dosage requirements for EE which does not exceed, in the most limiting manner, to no more than 15 mcg EE equivalent, (e.g., see present claims 9 and 11). If one were to consider the dosage amounts claimed by Cohen to be for mestranol, in order to compare such dosages to the presently claimed dosages, which are in terms of EE equivalents, then the dosage range of from 2 to 1000 mcg would be altered by the fact that the patentees teach that ethinylestradiol is twice as potent as mestranol, (col. 6, lines 2-3). Taking this into account, the dosage range of from 2 to 1000 mcg of mestranol would equate to 0.5 to 500 mcg of ethinylestradiol, (EE), which also meets the presently claimed dosage requirement of no more than 15 mcg EE equivalent.

Respecting the progestogen dosages taught by Cohen, it can be seen in his claim 14 that, taking into account the typographical error where "2500 mg" should read as ---2500 mcg---, (see col. 5, line 24), the progestogen dosage ranges from about 7.5 mcg to about 2500 mcg per 70 kg of body weight per day. In his claim 16, the progestogen is limited to either norethindrone or norgestrel. In order to compare from about 7.5 mcg to about 2500 mcg of either norethindrone or norgestrel to the presently claimed daily and cumulative dosage amounts of LNg, the following are relied on as conversion factors. First, if one considers the patentee's dosage to be in terms of norethindrone, to convert the such into a dosage range of LNg, Gast, (U.S. Patent No. 5,747,480) is relied on where it is taught that a 75 mcg dosage of LNg is equivalent to 250 mcg of norethindrone, ("NE"; see col. 5, lines 8-10). This conversion would equate to where 0.3 mg

LNg is equal to 1 mg of NE. Thus, in Cohen, the dosage of from about 7.5 mcg to about 2500 mcg for NE would be equal to about 2.25 mcg to about 750 mcg, (i.e., 0.00225 mg to about 0.75 mg), LNg. A LNg dosage range of from about 0.00225 mg/day to about 0.75 mg/day is encompassed by the present claims which recite "at least 1.0 mg levonorgestrel". Because the prior art employs the term "about", such is deemed sufficient to have suggested the claimed 1 mg dosage from a teaching of "about 0.75 mg". Also, if one were to multiple the dosage range of 0.00225 to about 0.75 mg/day by about 21 days, (i.e., the cycle length taught by Cohen at col. 4, lines 61-66 and col. 5, lines 12 and 13), which is encompassed in present claims 17-22, such would equal an amount of "about" 0.05 mg to about 15.75 mg of LNg. The upper dosage limit of "about 15.75 mg" is not seen to be patentably distinct from the presently claimed cumulative dosage requirement which exceeds 20 mg, (e.g., present claim 19).

Alternatively, because it appears that levonorgestrel is one of the two enantiomers in the racemic norgestrel compound of Cohen, it would seem that the dosage LNg would be one-half the dosage of norgestrel. Thus, the dosage of Cohen of from about 7.5 mcg to about 2500 mcg would be from about 3.75 mcg to about 1250 mcg or, in terms of milligrams as is presently claimed, from about 0.00375 mg to about 1.25 mg. Thus, the claimed daily dosage amount of "at least 1.5 mg", (e.g., present claim 5), is not seen to be patentably distinct from "about 1.25 mg" as suggested by Cohen. Also, by multiplying a dosage range of from about 0.00375 mg to about 1.25 mg by 21 days, a range of from about 0.078 to about 26.25 mg is calculated. The upper limit of about 26.25 mg clearly encompasses the presently claimed dosage which is exceeding 20 mg, (e.g., present claim 19).

Present claims 6 and 7 are **not** subject to the present rejection because a daily LNg dosage of at least 2.0 mg or at least 3.0 mg is neither taught nor suggested in the references of record.

Accordingly, for the above reasons, the present claims are deemed to be properly rejected.

Double Patenting

Claims 1-26 are is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,511,970 (Rodriguez, already of record). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed levonorgestrel is an enantiomer of the compound of the patented claims, i.e., norgestrel, and thus would have been present in the patented hormonal regimen. Also, the dosage amounts, whether daily or cumulative, of the present claims, for each of the progestogen and the estrogen component are not seen to be patentably distinct from the dosage requirements of the patented claims.

Applicant's comments at page 6 of the communication filed April 18, 2006 have been carefully considered, but fail to persuade the Examiner of error. In particular, the above position taken by the Examiner no longer relies on the teachings of Chien, as in the previous Office action. Accordingly, Applicant's comments which are predicated on Chien are no longer germane. For the reasons above, however, it is deemed that the subject matter of the '970 patent and the presently claimed subject matter is not patentably distinct.

Accordingly, the claims are deemed properly rejected.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

July 22, 2006